

Use of SPL Data in Healthcare Information Systems

Part One



A Downstream Use of SPL Subgroup Publication

Table of Contents

<u>DATA FLOW - SHARING SPL INFORMATION</u>	<u>2</u>
<u>DAILYMED</u>	<u>3</u>
<u>THE EPRESCRIBING-RXNORM-SPL CONNECTION</u>	<u>4</u>
<u>PHARMACOLOGIC CLASS INDEXING SPL</u>	<u>5</u>
<u>BILLING UNIT INDEXING SPL</u>	<u>7</u>

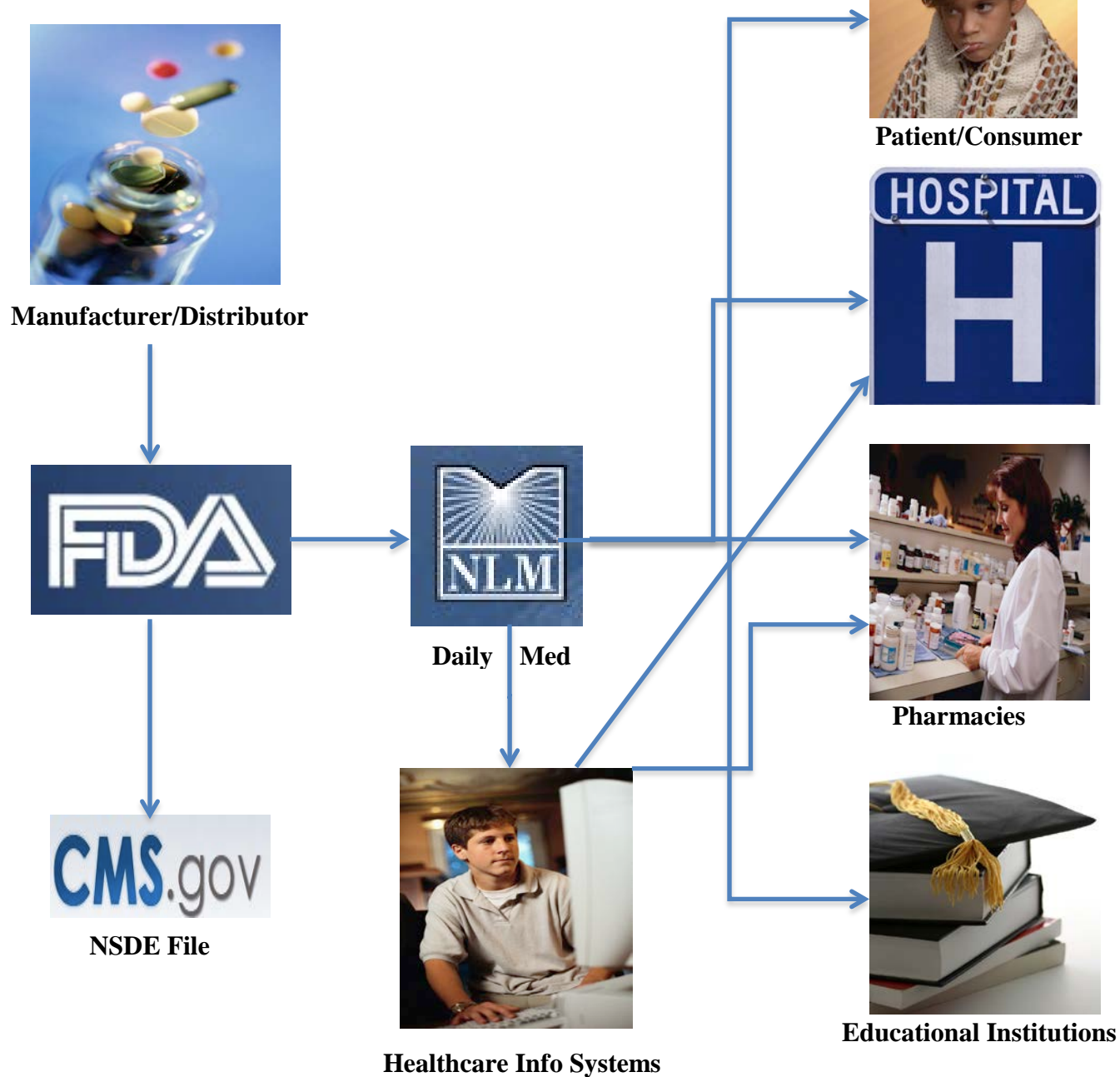
Note: The purpose of the “Use of SPL Data in Healthcare Information Systems” SPL eBook series is to provide **quick reference guides** for downstream users of SPL data and other entities which express an interest in the utilization of SPL information.

For more detailed information regarding the SPL standard and its implementation, please use these web resources:

1. FDA’s SPL web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>
2. SPL Working Group Wiki web page: <https://spl-work-group.wikispaces.com/>

Data Flow - Sharing SPL Information

Note: This chart should assist you in tracing the basic flow of SPL data from its origin to **some** of its end points.



DailyMed



As indicated in the SPL data flow chart on the previous page of this eBook, manufacturers/distributors submit SPL files to FDA to be transmitted and posted on DailyMed. (DailyMed receives SPL files once each business day.)

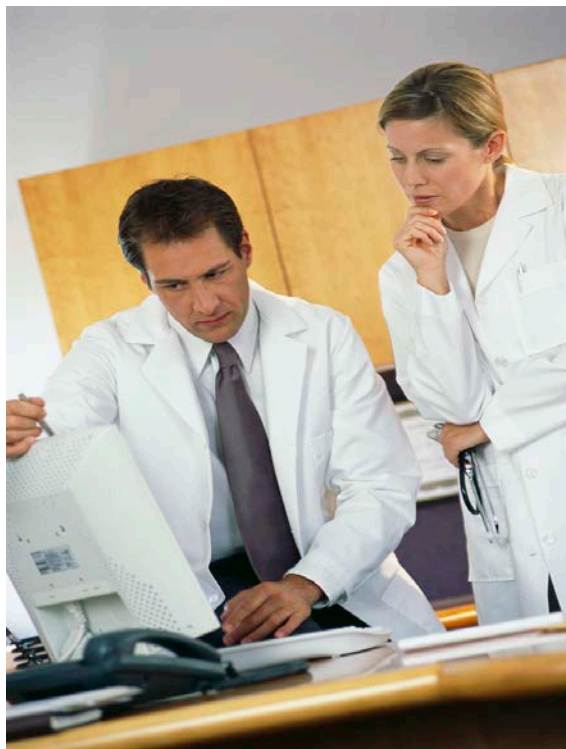
Via a formal agreement with FDA, National Library of Medicine (NLM) makes the SPL files available at no cost using downloadable zip files which can be imported into clinical decision support systems and other healthcare information systems. NLM also performs the role of healthcare information provider through its DailyMed website.

For more information about the DailyMed initiative, see this 2005 FDA press release:
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108509.htm>.

For more details about the DailyMed website, please visit the DailyMed web page:
<http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

Here are the hyperlinks to the web pages with the downloadable packages of SPL files:
<http://dailymed.nlm.nih.gov/dailymed/downloadLabels.cfm> and
<http://dailymed.nlm.nih.gov/dailymed/downloadIndexing.cfm>.

The ePrescribing-RxNorm-SPL Connection

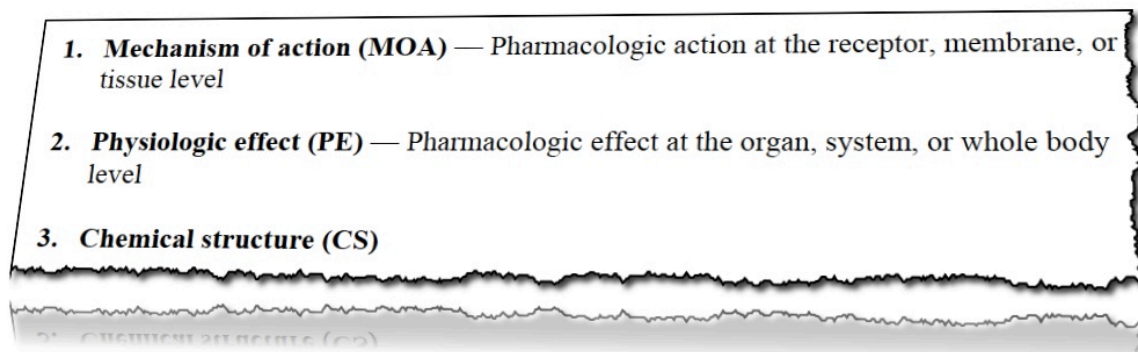


SPL is one of eleven data sources NLM utilizes for RxNorm. Some of the information in drug product SPL files may be used to generate RxNorm data. For example, if a drug company submits an SPL file for a newly marketed drug product for which information does not already exist in the RxNorm database, once the file has been transmitted for posting on DailyMed, NLM may import the file's data from their MTHSPL database to generate an RxNorm code for the drug product. The RxNorm codes in electronic prescribing systems may be used by doctors to provide a clinical description of a drug product.

For more information regarding the electronic prescribing-RxNorm-SPL connection, see a 2004 National Committee for Vital and Health Statistics letter (<http://www.ncvhs.hhs.gov/040902lt2.htm>)

For an overview of RxNorm, please visit NLM's RxNorm website: <http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>.

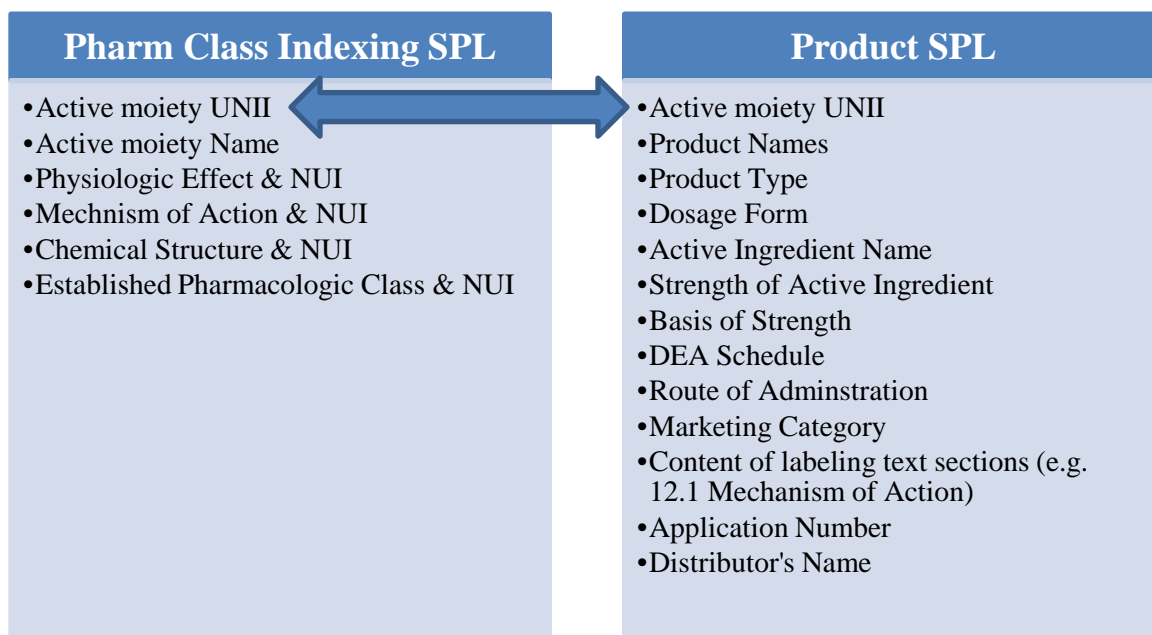
Pharmacologic Class Indexing SPL



Once imported into a database which contains information from both indexing and product SPL files downloaded from DailyMed, the data in indexing SPL files can be used to enhance automated queries of clinical decision support systems that have features such as the searching and sorting of electronic content of drug product labeling data from products' SPL files.

Searching for FDA-approved human prescription drug products which have a certain mechanism of action, physiologic effect, chemical structure, and/or established pharmacologic class (data elements in the pharmacologic class indexing SPL file) is an example of how the pharmacologic class indexing SPL data may be utilized to enhance the automated queries of the electronic content of product labeling data.

The graphic on the next page shows that an active moiety's Unique Ingredient Identifier (UNII) can serve as a link between the pharmacologic class indexing and product SPL documents.



Note: Not all data elements in the pharmacologic class indexing and product SPL files are listed in the above graphic.

Details regarding the indexing SPL initiative are included in the Guidance for Industry – Indexing Structured Product Labeling which is accessible via this hyperlink:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072317.pdf>.

More information about pharmacologic class indexing SPL files is available in the Indexing SPL Fact Sheet accessible via a hyperlink located under the web page heading “Resources” on this web page:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm> as well as the Pharmacologic Class Indexing SPL web page:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162549.htm>.

The downloadable package of the pharmacologic class indexing SPL files is accessible via this DailyMed web page:

<http://dailymed.nlm.nih.gov/dailymed/downloadIndexing.cfm>.

Billing Unit Indexing SPL

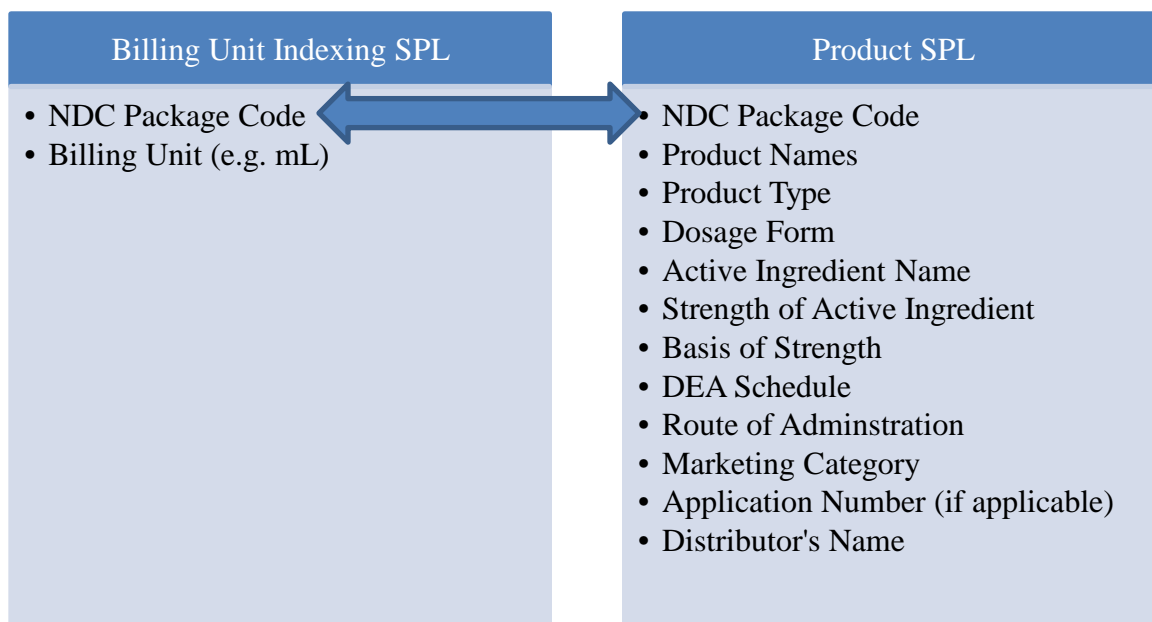


Via a formal agreement, FDA and National Council for Prescription Drug Programs (NCPDP) make billing unit information in SPL format available for download from DailyMed at no cost. Each month, NCPDP provides FDA with data for the billing units associated with drug packages. Using that data, FDA's system automatically generates a billing unit indexing SPL file for each three-segment National Drug Code (NDC) package code for which a billing unit indexing SPL file does not already exist on DailyMed. Each month, new and occasionally revised billing unit indexing SPL files are transmitted to DailyMed.

Billing unit indexing SPL files and product SPL files may be downloaded from DailyMed and stored in a database to automatically link the data utilizing an NDC package code as a linking identifier. Each NDC package code is included in only one billing unit indexing SPL file and in only one product SPL file posted on DailyMed.

Once the data from the billing unit indexing and product SPL files are both stored in a database, one can generate reports to for example, view the product names associated with the billing unit/NDC data relationships.

See graphic below for an example of **some** of the data included in both the billing unit indexing and product SPL files.



Note: Not all data elements in the billing unit indexing and product SPL files are listed in the above graphic.

A brief overview of NCPDP's billing unit standard is accessible via this hyperlink: http://www.ncdp.org/PDF/BUS_overview.pdf.

More information about billing unit indexing SPL files is available in the Indexing SPL Fact Sheet accessible via a hyperlink located under the web page heading "Resources" on this web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

The downloadable package of the billing unit indexing SPL files is accessible via this DailyMed web page: <http://dailymed.nlm.nih.gov/dailymed/downloadIndexing.cfm>.